



Randomized Controlled Trial Evaluating Ovulation Response after Myo Inositol versus Metformin in Women with Polycystic Ovary Syndrome.

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Abstract

Background:

One of the most prevalent endocrine conditions affecting women of reproductive age is polycystic ovary syndrome (PCOS), which is a primary contributor to anovulatory infertility. One important factor in the pathophysiology of PCOS is insulin resistance. While myo-inositol has lately surfaced as a viable substitute for enhancing ovulatory function, metformin has long been utilized as an insulin sensitizer.

Objective:

To compare the ovulation response of Myo-inositol and Metformin in women with PCOS.

Methods:

Over the course of four months, 200 women with PCOS were included in a research trial. Two groups of one hundred each were randomly selected from among the participants. Group B was given 500 mg of metformin three times a day, while Group A was given 2 g of myo-inositol twice a day. Follicle monitoring and blood progesterone levels were used to track ovulation. Pregnancy rate, menstrual regularity, and ovulation rate were among the results. The chi-square test was used for statistical analysis, and $p < 0.05$ was deemed statistically significant.

Results:

Compared to 48% of women in the Metformin group, 62% of women in the Myo-inositol group experienced ovulation. Compared to 18% of women taking metformin, 28% of women taking myo-inositol became pregnant. Myo-inositol appeared to improve the difference in ovulation rate ($p = 0.064$). Although the Myo-inositol group had a greater pregnancy rate, the difference was not statistically significant ($p = 0.13$).

Conclusion:

In women with PCOS, myo-inositol produced better ovulation and pregnancy outcomes than metformin. For PCOS patients, it can be regarded as an efficient and well-tolerated substitute for ovulation induction.

Recommendation:

Myo-inositol may be considered a preferable first-line therapy for ovulation induction in women with polycystic ovary syndrome due to its favorable efficacy and tolerability profile.

Keywords: Polycystic Ovary Syndrome, Myo-inositol, Metformin, ovulation induction, infertility.

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Introduction

About 6–15% of women who are of reproductive age have PCOS, a complicated endocrine condition. It is distinguished by polycystic ovarian morphology, chronic anovulation, and hyperandrogenism. (1). Metabolic problems, including insulin resistance, obesity, and decreased glucose tolerance, are also linked to PCOS. Because it disrupts follicular maturation and increases ovarian androgen production, insulin resistance is a key factor in the pathophysiology of PCOS. As a result, insulin-sensitizing medications are now a crucial part of managing PCOS.

Metformin has been used extensively to help women with PCOS regain ovulation and increase insulin sensitivity. However, long-term use may be restricted due to poor tolerance and gastrointestinal adverse effects. (2).

Recently, myo-inositol, a naturally occurring insulin sensitizer, has drawn interest as a potential PCOS treatment. In insulin signaling pathways, it functions as a second messenger and may enhance ovulation, hormonal balance, and ovarian function. According to a number of studies, myo-inositol had fewer adverse effects than metformin while also improving ovulation and reproductive outcomes. There is still little data comparing the two treatments, though (3).

In order to assess the ovulation response of myo-inositol in comparison to metformin in women with PCOS, the current clinical experiment was carried out.

Materials and Methods

Study Design

This study was conducted as a randomized controlled parallel group clinical trial with a 1:1 allocation ratio.

Study Setting and Duration

The study was carried out in the Department of Obstetrics and Gynaecology at DRIEMS Institute of Health Sciences and Hospital, Odisha, India, from January 2025 to April 2025.

Study Population

Women attending the gynecology outpatient department who were diagnosed with polycystic ovary syndrome and presented with infertility due to anovulation were included in the study.

Sample Size

A total of 200 participants were included in the study. The sample size was calculated based on an expected difference in ovulation rates between the two groups with 80 percent power and a 5 percent level of significance.

Inclusion Criteria

- Women aged 18 to 35 years
- Diagnosed with polycystic ovary syndrome according to Rotterdam criteria
- Infertility due to anovulation
- Not on hormonal treatment for at least three months prior to enrollment

Exclusion Criteria

- Diabetes mellitus
- Thyroid disorders
- Hyperprolactinemia
- Severe systemic illness
- Previous ovarian surgery

Randomization and Allocation Concealment

Participants were randomly assigned to two groups using a computer-generated random number sequence. Allocation concealment was ensured using sealed opaque envelopes, which were opened at the time of enrollment.

Blinding

This was an open-label study as blinding of participants and treating clinicians was not feasible due to the nature of the interventions.

Intervention

Participants were divided into two groups:

- Group A received Myo-inositol 2 grams twice daily
- Group B received Metformin 500 milligrams three times daily

The treatment was continued for a duration of four months.

Outcome Measures

The primary outcome was ovulation rate assessed by follicular monitoring and serum progesterone levels.

Secondary outcomes included:

- Pregnancy rate



- Menstrual cycle regularity

A p-value of less than 0.05 was considered statistically significant.

Data Collection Procedure

Baseline demographic and clinical data, including age, body mass index, x and duration of infertility, were recorded. Participants were followed up monthly for assessment of ovulation and menstrual regularity.

Ethical Considerations

The study was conducted after obtaining approval from the institutional ethics committee. Written informed consent was obtained from all participants prior to enrollment.

Statistical Analysis

Data were analyzed using statistical software. Continuous variables were expressed as means with standard deviation, and categorical variables as percentages. The chi-square test was used to compare categorical variables between groups.

Results

A total of 220 patients were assessed for eligibility, of which 200 were included and randomized equally into two groups with no loss to follow-up.

Table 1: Baseline Characteristics of Participants

Parameter	Myo-inositol (n=100)	Metformin (n=100)	p value
Mean Age (years)	26.4 ± 3.2	27.1 ± 3.5	0.18
Mean BMI (kg/m ²)	27.3 ± 2.6	27.8 ± 2.9	0.29
Duration of infertility (years)	3.1 ± 1.2	3.3 ± 1.4	0.35

There was no statistically significant difference between the two groups in terms of age, body mass index, and duration of infertility, indicating comparability at baseline. (No significant difference between groups)

Table 2: Ovulation Response

Ovulation was observed in 62 percent of women in the Myo-inositol group compared to 48 percent in the Metformin group. However, this difference did not reach statistical significance with a p-value of 0.064.

Treatment	Ovulation	No Ovulation	Total	p value
Myo-inositol	62	38	100	
Metformin	48	52	100	
Total	110	90	200	0.064

Table 3: Pregnancy Outcome

Pregnancy occurred in 28 percent of women in the Myo-inositol group compared to 18 percent in the Metformin group. The difference was not statistically significant, with a p-value of 0.13

Treatment	Pregnancy	No Pregnancy	Total	p value
Myo-inositol	28	72	100	
Metformin	18	82	100	
Total	46	154	200	0.13



Table 4: Menstrual Regularity After Treatment

Menstrual cycle regularity improved significantly in the Myo inositol group, with 70 percent achieving regular cycles compared to 55 percent in the Metformin group, with a statistically significant p value of 0.03.

Treatment	Regular Cycles	Irregular Cycles	Total	p value
Myo-inositol	70	30	100	
Metformin	55	45	100	
Total	125	75	200	0.03

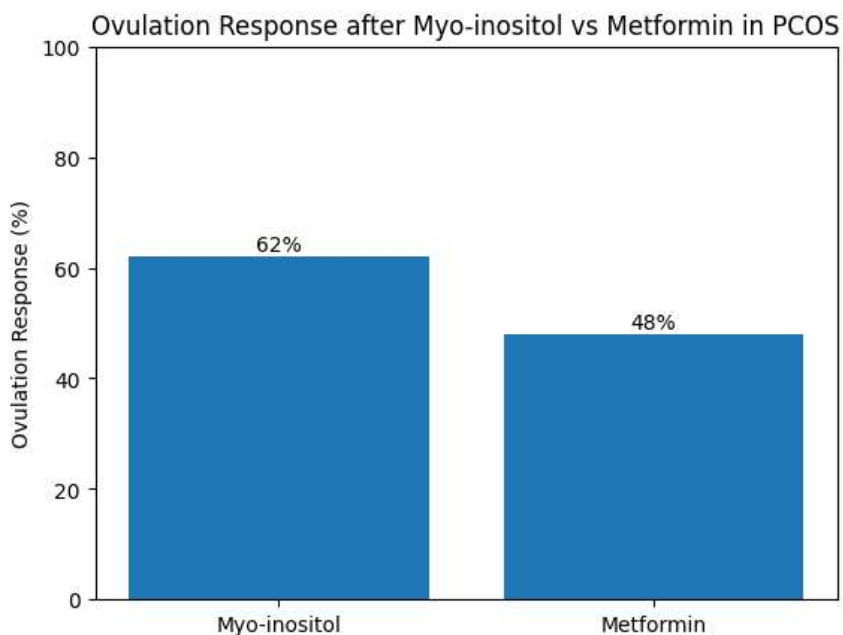


Figure 1: Ovulation Response

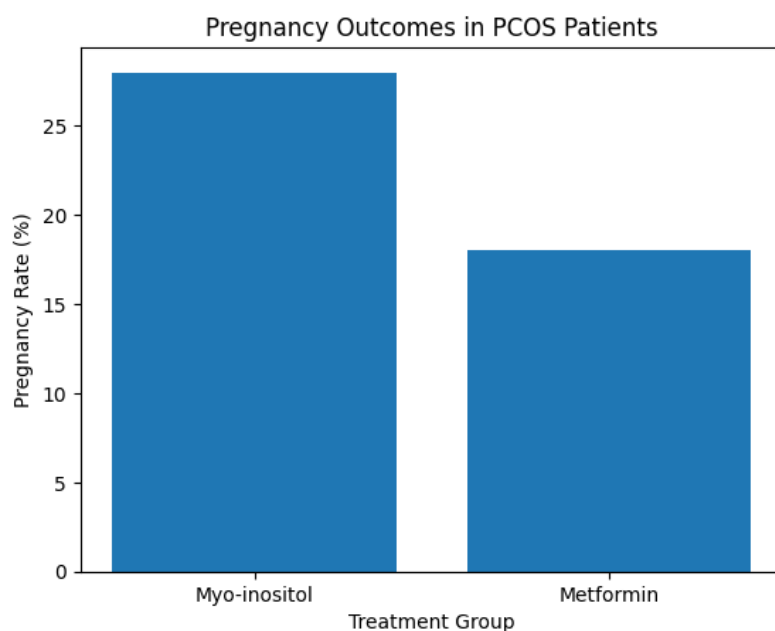


Figure 2: Pregnancy Outcomes

Discussion

The goal of the current clinical experiment was to examine the effects of metformin and myo-inositol on ovulation in women with polycystic ovarian syndrome (PCOS). Since insulin resistance, hyperandrogenism, and ovulatory dysfunction are frequently linked to PCOS, ovulation induction is a crucial part of treatment. (4). According to the study's findings, women treated with myo-inositol had a better ovulatory response than those treated with metformin. In the current study, 48% of women in the Metformin group had ovulation, while 62% of women in the Myo-inositol group did so. According to these results, myo-inositol might be more successful in enhancing ovulatory function in PCOS-afflicted women. Additionally, women treated with Myo-inositol had a greater pregnancy rate (28%) than those treated with Metformin (18%). The data show a positive trend toward better reproductive outcomes with Myo-inositol therapy, even if the difference in pregnancy rates between the two groups was not statistically significant. (5). Furthermore, when compared to metformin, myo-inositol showed a notable improvement in the regularity of the menstrual cycle. For women with PCOS, regular menstrual periods are a key sign of hormonal balance and improved ovulatory function. Myo-inositol's function in insulin

signaling pathways explains its advantageous benefits. In insulin signaling, myo-inositol serves as a second messenger and enhances insulin sensitivity. It helps restore normal follicular growth and ovulation by lowering ovarian androgen production through the reduction of insulin resistance and hyperinsulinemia. (6).

These results are in line with a number of earlier studies that found that women with PCOS who received Myo-inositol experienced better ovulation rates and more regular periods. When compared to metformin, myo-inositol has a reduced incidence of gastrointestinal side effects and higher tolerance, which is another significant benefit shown in clinical practice (7).

A single-center study design, a very brief follow-up period, and the lack of a long-term metabolic outcome evaluation are some of the study's drawbacks. To verify the effectiveness and safety of myo-inositol in the treatment of PCOS, more extensive randomized controlled trials with longer follow-up times are therefore needed. (8).

Conclusion

In women with PCOS, myo-inositol outperformed metformin in terms of ovulation response, menstrual regularity, and pregnancy rates. Myo-inositol may be a good



substitute for metformin in PCOS patients' ovulation induction due to its good efficacy and safety profile.

Trial Registration

“This trial was not registered.”

Funding

“No funding was received for this study.”

Conflict of Interest

“The authors declare no conflict of interest.”

Data Availability

“Data supporting the findings are available from the corresponding author upon reasonable request.”

Acknowledgement

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